

Structured Product Labeling (SPL) OTC Sub-team Teleconference
April 11, 2011, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Cheryl Blik, Teva Pharmaceuticals USA
-  Terry Brunone, GlaxoSmithKline
-  Gail Burke, Procter & Gamble
-  Pete Carlson, Ecolab
-  Amy Deuchler, Medline Industries, Inc.
-  Lisa Fields, Blistex, Inc.
-  Michele Hewitt, Sandoz, Inc., Broomfield
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Carolyn Lindsay, Cardinal Health
-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team leader)
-  Wafa Nguyen, Qualitest Pharmaceuticals
-  Kathy Olgers, Perrigo Company
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Gary Saner, Reed Technologies and Information Services, Inc.
-  Dave Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Christie Simpson, Reckitt Benckiser, Inc.
-  Sandra Spiewak, Reed Technology and Information Services
-  Carl Strotz, Pfizer Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Cynthia Thompson, Kimberly-Clark Corporation
-  Carey Wilson, Intragras
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: May 9, 2011, 1:00pm ET (unless cancelled).

Standing calls for 2011 will be held on the second Monday of each month only and will be cancelled as appropriate.

III. Debrief from ER/DL Sub-team Call with FDA Staff March 30, 2011 (1:00 – 2:30 pm ET)

- FDA staff from Drug Registration and Listing System (DRLS), CBER, CVM, Compliance/Imports, and Data Standards participated on the teleconference. Summary notes from the ER/DL call are in preparation and will be posted to the Wikipage once the FDA call participants have had a chance to review the recap. The summary will also be circulated to the sub-team.
- Questions and scenarios addressed during the call were circulated to SPL OTC sub-team members prior to the call. (*Provided as separate attachment*)
- Highlights from some of the points discussed on the call (*not intended to reflect official FDA policy or position; not intended to represent quotes or verbatims from the discussion*).
 - New marketing categories
 - apply to human OTC drugs only
 - Content of Labeling (CoL) not required, only principle display panel (PDP) image
 - information not posted to NDC directory, DailyMed, or Labels.gov
 - Bulk Ingredient/Drugs for Further Processing category
 - these are drugs/ingredients that are **not** ready for human use
 - listings should still provide the source NDC for the product
 - Inactive ingredients
 - agreement on points as mentioned during the SPL OTC sub-team call on March 14, 2011
 - Drug listing by a manufacturer vs. private label distributor (PLD)
 - manufacturers should list for their PLDs (using the PLD's NDC) if the PLD chooses not to complete the listing
 - FDA wants as much information about the supply chain as possible
 - FDA is also in the process of updating section 207 of regulations and will consider revising the guidance document
 - Issue resolution for imports
 - district manager/officer makes the final decision to resolve disputes
 - import staff checks for “adequacy of listing” at the time of importation, not just drug listing and establishment registrations information
 - Resolving issues regarding DUNS information
 - contact Dun & Bradstreet to resolve the issue
- It was suggested by one SPL OTC sub-team member (via email) that, to the extent possible and appropriate, FDA be encouraged to harmonize the regulations & guidances.

- The ER/DL sub-team intends to have periodic calls with agency staff similar to the March call so members were encouraged to submit questions, scenarios, and concerns to Pat Cowall-Hanover, Terry Brunone, Paula Markert, and/or Marcia Howard in anticipation of the next teleconference (likely summer 2011).

IV. SPL Educational Forums/Information (*For Your Information*)

- A. **FDA Training Sessions:** Please visit the Data Standards Council website for details about upcoming agency training opportunities.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 240184

Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

SPL Working Group Wikipage: <http://spl-working-group.wikispaces.com/Drug+Listing> (no log-on or password needed).

- C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover (COWALL-HANOVER.PATRICIA.L@LILLY.COM) or Jessica Dunn Skorupski if you want to get the email information (JSkorups@its.jnj.com).

Note: A representative from CMS is expected to participate on the April 27, 2011, call.

- D. **SPL Generics Sub-team calls:** Not currently holding regular calls.
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

- E. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST
Please email Sub-team leader Myron Finseth (myron.finseth@medtronic.com) if you want to join this sub-team.

Telephone Number: 770-657-9270
Participant passcode: 745896

- F. **SPL Usage Discussion Group**
Please email or call Terry Brunone (Theresa.M.Brunone@gsk.com; +1-215-751-3210) or Gary Saner (gsaner@reedtech.com; +1-610-731-7192) if you wish to join the discussion group.

- G. **Homeopathic Sub-team** (*new sub-team; not replacing SPL OTC sub-team*)
Next call: **April 21, 2011, 1:00 – 2:00 pm ET.**

Contact sub-team leader Travis Borchardt (tborchardt@enzy.com) if you wish to join this sub-team.

MDH/04-14-11

SPL OTC Sub-team 11 April 2011 041411.doc
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